DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration
Los Angeles District 94410d

19701 Fairchild
Irvine, California 92612-2506
Telephone (949) 608-2900

WARNING LETTER

November 24, 2003

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Johannes R. Wiesbauer
President and C.E.O
American Medical Devices, Inc.
287 South Stoddard
San Bernardino, CA 92401

WL 09-04

Dear Mr. Wiesbauer:

Our review of information collected during an inspection of your medical device firm located in San Bernardino, California on September 15-18, 2003 revealed that your firm assembles and distributes medical procedure kits. These products are devices as defined by Section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act).

The above-stated inspection disclosed that devices are adulterated within the meaning of Section 501(h) of the Act, in that the methods used in, or the facilities or controls used for manufacturing, packing, and storage are not in conformance with the Current Good Manufacturing Practice (CGMP) requirements for the Quality System Regulation for medical devices, as specified in Title 21, Code of Federal Regulations (CFR), Part 820. At the close of the inspection, you were issued a Form FDA-483 which delineated a number of significant CGMP inspectional observations which include, but are not limited to, the following:

1. Management with executive responsibility has not ensured that quality system requirements are effectively established and maintained at all levels of the organization [21 CFR 820.20]. Specifically, procedures for management review have not been established to ensure that the quality system satisfies the requirements of the quality system requirements and the established quality policy and objectives. No management reviews have been conducted since 7/8/94.

2. Quality audits have not been conducted to verify that the quality system is effective in fulfilling the quality system objectives [21 CFR 820.22].

3. Procedures were not established for monitoring and control of process parameters for validated processes [21 CFR 820.75(b)]. Specifically, procedures for revalidation of the ethylene oxide sterilization process (EtO) used to sterilize finished device kits have not been established and there is no evidence of the EtO sterilization process has been revalidated since 4/1996. Documentation was collected which shows that several current sterilization parameters are above or below the parameters described in the last validation report.

4. Environmental control systems have not been inspected periodically to verify that the system including necessary equipment is adequate and functioning properly [21 CFR 820.70(c)]. Specifically, the Class 100,000 cleanroom was not recertified between 3/97 to 9/2003 and no documented evidence that demonstrates that any environmental monitoring is conducted by the firm.

5. Procedures for implementing corrective and preventive action addressing the analysis of sources of quality data to identify existing and potential causes of nonconforming product or other quality problems [21 CFR 820.100].

6. Product was not stored to facilitate proper stock rotation and to assess its condition as appropriate [21 CFR 150(a)]. Specifically, two cases of expired components were found among current inventory of component materials.

7. Complaint handling procedures have not been defined to ensure that all complaints are evaluated to determine whether the complaint should be filed as a Medical Device Report (MDR) and there are no MDR procedures [21 CFR 820.198(a)(3)].

This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to each requirement of the Act and the regulations. The specific violations noted in this letter and in the Form FDA 483 issued at the conclusion of the inspection may be symptomatic of serious underlying problems in your firm's manufacturing and quality assurance system. You are responsible for investigating and determining the causes of the violations identified by the FDA. If the causes are determined to be systems problems, you must promptly initiate permanent corrective actions.

Federal Agencies are advised of the issuance of all Warning Letters about devices so that they may take this information into account when considering the award of contracts. Additionally, no pre-market submissions for devices to which the GMP deficiencies are reasonably related will be cleared until the violations have been corrected. Also, no requests for Certificates For Exportability will be approved until the violations related to the subject devices have been corrected.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action being initiated by the Food and Drug Administration without further notice. These actions include, but are not limited to, seizure, injunction, and/or civil penalties.

In addition, you received a previous Warning Letter on June 28, 1994 regarding your firm's failure to comply with the Good Manufacturing Practice Requirements for Medical Devices as formerly set forth in 21 CFR Part 820. Several of the current inspectional observations regarding your medical device operation are similar to those previously cited in the earlier Warning Letter. This presents the District with serious concerns regarding your firm's ability to undertake permanent corrective and preventive action on your Quality System. Because of these concerns, the District believes a regulatory meeting is warranted at this time to discuss your compliance with the Quality System Regulation.

Please contact Senior Compliance Officer, Dannie E. Rowland at (949) 798-7649 to make the necessary arrangements for the meeting or if you have any questions or need clarification regarding this letter. This meeting does not relieve you of the responsibility to notify this office in writing within 15 working days of receipt of this letter, of the specific steps you have taken to correct the noted violations, including an explanation of each step being taken to identify and make corrections to any underlying systems problems necessary to assure that similar violations will not recur. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed.

Please submit your response to:

Acting Director, Compliance Branch
Food and Drug Administration
19701 Fairchild
Irvine, CA 92612-2445

Sincerely,

Alonza E. Cruse
District Director
Los Angeles District Office

Cc: State Department of Public Health
Environmental Health Services
Attn: Chief, Food and Drug Branch
601 North 7th Street, MS-35
Sacramento, CA 94234-7320